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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,171	02/04/2002	Sally Mossman	210121.721	8073

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/068,171	MOSSMAN ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address.--

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91,94,96-100,105-113 and 117-126* is/are pending in the application.

4a) Of the above claim(s) *96-98,100,108-110,112,113,120 and 122-126* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *91,94,99,105-107,111,117-119,121* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 14, 2007 has been entered.

2. The terminal disclaimer filed on May 14, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 7,030,094 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 91, 92, 94, 99, 105, 111, 117, 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,113,918, IDS) in view of Kensil et al. (US 5,057,540), and in further view of applicants' own admission..

3. Johnson et al. teach that aminoalkyl glucosamine phosphates, including the particular elected AGP herein, are known as adjuvant, and immunoeffectors. Johnson further teaches that the adjuvants composition may be in various forms including oil-in-water or water-in-oil emulsions, aqueous composition, liposome, etc; vaccine composition comprising the AGP and

antigen. Johnson et al. also teach a method of using the AGP for enhancing the immune response of an animal. See, particularly, the abstract, columns 2-5, example 20 in column 42, and the claims.

4. Johnson et al do not teach expressly the employment of a combination of AGP and Quil A for enhancing the immune response.

5. However, Kensil et al. teaches that Quil A, and its' fractions including QS 21, is known to be useful as immune adjuvant, which is useful for stimulating immune response, particularly co-administered with antigen. The adjuvant may be administered individually or admixed with a variety of other adjuvants to achieve the enhancements of the immune response to antigen, including those of tuberculosis. See, particularly, the abstract, column 6, line 54 to column 7, lines 40, and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a composition comprising the two adjuvants herein, i.e., Quil A and the particular AGP herein, and optionally further comprising antigen, such as those for tuberculosis.

A person of ordinary skill in the art would have been motivated to composition comprising the two adjuvants herein, i.e., Quil A and the particular AGP herein, and optionally further comprising antigen, such as those for tuberculosis because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus , the claimed invention which is a combination of two known adjuvants sets forth prima facie obvious

subject matter. See In re Kerkhoven, 205 USPQ 1069. Further, the prior arts teach the concomitant application of Quil A with other adjuvants. As to the particularly amount of each active ingredients herein, note, the optimization of a result effective parameter, e.g., amounts of the active ingredients in a pharmaceutical composition, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. With respect to the particular antigen herein, note applicants acknowledged that such antigen was known in the art. See the example 1 herein at page 74. Using a known antigen properly is within the skill of artisan. As to the recitation "enhancing CTL immune response", in the preamble of the claims, it is noted that this recitation gives little "life and meaning' to the claims as it does not limits any steps involved in the claimed method, or the subject being treated.

6. Claims 106, 107, 118, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,113,918, IDS) in view of Kensil et al. (US 5,057,540), and in further view of applicants' own admission as set forth above, and in further view of De Vrier et al.

7. Johnson et al. and Kensil et al. as a whole do not teach expressly the employment of phospholipid in the immunogenic composition employed herein.

8. However, De Vries et al. disclosed that for immunogenic composition with antigens, surfactants, such as phospholipids, are known to be useful, particularly with saponin. See, particularly, the abstract, col. 3, lines line 9-62, and the claims.

9.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to incorporate surfactants, such as phospholipids in the aqueous immunogenic composition.

A person of ordinary skill in the art would have been motivated to incorporate surfactants, such as phospholipids in the aqueous immunogenic composition because surfactants, such as phospholipids, are known to be useful in such composition for stabilizing the antigen containing composition.

10. Claims 91, 92, 94-95, 99, 102, 105, 111, 114, 117, 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,113,918, IDS) in view of Kensil et al. (US 5,057,540), and in further view of applicants' own admission, for reasons discussed above, and in further view of Johnson (US 2001/0053363, IDS) or Mossman et al. (WO 02/03961, IDS).

11. Johnson and Mossman et al. provide further motivation to combine the two adjuvants, AGP and Quil A. Particularly, Mossman et al. teach that AGP and Quil A are useful together and disclose a composition comprising both AGP and Quil A, See, particularly, claims 32 and 42. The AGP disclosed by Mossman including those herein employed see the figures. Johnson also discloses that saponin and AGP adjuvants are useful together and may produce synergistic effect. See, particularly example 7 at pages 28-29. Therefore, one of ordinary skill in the art, would have been further motivated to combine the two adjuvants as herein claimed, since it have been shown that two adjuvants are useful together as have been expected, and may produce synergistic effect.

12. Claims 106, 107, 118, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (US 6,113,918, IDS) in view of Kensil et al. (US 5,057,540), and in further view of applicants' own admission as set forth above, and in further view of De Vrier et al, for

reasons set forth above, and in further view of Johnson (US 2001/0053363, IDS) or Mossman et al. (WO 02/03961, IDS).

13. Johnson and Mossman et al. provide further motivation to combine the two adjuvants, AGP and Quil A. Particularly, Mossman et al. teach that AGP and Quil A are useful together and disclose a composition comprising both AGP and Quil A, See, particularly, claims 32 and 42. The AGP disclosed by Mossman including those herein employed see the figures. Johnson also discloses that saponin and AGP adjuvants are useful together and may produce synergistic effect. See, particularly example 7 at pages 28-29. Therefore, one of ordinary skill in the art, would have been further motivated to combine the two adjuvants as herein claimed, since it have been shown that two adjuvants are useful together as have been expected, and may produce synergistic effect.

Response to the Arguments

Applicants' amendments and remarks submitted May 14, 2007 have been fully considered, but are not persuasive.

14. As to the new limitation, "enhancing a CTL immune response in an animal", note a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

15. The evidences for unobviousness presented in the application and in the declaration on the record have been fully considered. However, when all of the evidence is considered, the

totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness. Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). Further, A DECLARATION UNDER 37 CFR 1.132 must compare the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case if obviousness. See, MPEP 716.02 (e). Applicants assert a synergistic effect of claimed combination in the aspect of enhancing CTL immune response. In the examiner's view, the evidences on the record fails to establish a prima facie case of unexpected and significant benefit residing in the claimed invention. *The claims must be commensurate in the scope with any evidence of unexpected results*. There is no rationale that the synergistic effects as presented in the declaration of August 24, 2006 would be extrapolated to all the Quil A fractions herein and to all the AGP encompassed by the claims. Particularly, it has been suggested in the art to use the combination of two adjuvants. One must compare the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case if obviousness. Kensil et al. teaches the concomitant application of Quil A with other adjuvants. Johnson and Mossman et al. provide further motivation to combine the two adjuvants, AGP and Quil A. There is no evidence that the synergistic effect is unique and unexpected compared to the other combination taught or suggested by Kensil et al., Johnson, or Mossman. Finally, it is not clear as to how and why the asserted synergistic effects are practically significant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. /SHENGJUN WANG/
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617